UNITED STATES DEPARTMENT OF COMMERCE Patent and Trademark Office

ASSISTANT SECRETARY AND COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

#13

February 10, 1989

Mr. Ronald Wilson Health Assessment Policy Staff Office of Health Affairs Food and Drug Administration 5600 Fishers Lane Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 4,396,598, issued August 2, 1983, was filed on February 9, 1989 under Title II of Public Law 98-417.

The assistance of your Office is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC 156(g) before its commecial marketing or use. Since a determination has not been made whether the patent is question claims a product or method of using a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 USC 156.

C. E. Van Hom

Charles E. Van Horn
Deputy Solicitor
Office of the Solicitor
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